

REMARKS***Status of Claims***

Claims 21, 23-27 and 41-44 are pending in this application.

Claim Rejections

Claims 21, 23-27 and 41-44 stand rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,555,520 ("the '520 patent") as evidenced by Bost *et al.*, IMMUNOL. INVEST. 17: 577-586 (1988) and Bendayan *et al.*, J. HISTOCHEM. CYTOCHEM. 43: 881-886 (1995). Applicants respectfully traverse this rejection.

Underlying this lack of novelty rejection is the premise that, because the 60/101,318 provisional application ("the '318 provisional application") allegedly fails to disclose a specific, substantial and credible utility for the claimed invention, the claimed invention does not have priority to the '318 provisional application. Applicants respectfully disagree with the Examiner's conclusion.

At p. 3 of the Office Action, the Examiner states that "the skilled artisan would not know how to use the claimed antibodies that bind SEQ ID NO: 2." At p. 5 of the Office Action, the Examiner further states that the activities ascribed to IL-B50 in the '318 provisional application are "general activities that would apply to virtually any member of the hematopoietin family of cytokines, and are not specific to the IL-B50 polypeptide," and the skilled practitioner would have to perform research to discover what effects IL-B50 shares with IL-7.

The Examiner points to the fact that cytokines encompass a wide and diverse range of activities; however the '318 provisional application does not assert that IL-B50 is homologous to all cytokines or that it shares the biological activities of all cytokines. Instead, the '318 provisional application specifically asserts that IL-B50 is homologous to IL-7, a specific cytokine, and that IL-B50 is expected to share functional properties with IL-7. Specifically, the application asserts that it is likely that IL-B50 has stimulatory effects on hematopoietic cells (e.g. T-cells and B-cells). To support a patent claim, applicants need only demonstrate sufficient utility for one purpose.* *See Raytheon Co. v. Roper Corp.*, 724 F.2d 951, 220

* Thus, the fact that the specification states that IL-B50 can stimulate or inhibit hematopoietic cells is irrelevant. Moreover, a post-filing publication (Osborn et al., *Blood* 103(3):843-851 (2004) Exhibit A) confirms that IL-B50 can *stimulate or inhibit* hematopoietic cells as asserted in the application.

USPQ 592 (Fed. Cir. 1983) ("When a properly claimed invention meets at least one stated objective, utility under § 101 is clearly shown."); *Standard Oil Co. v. Montedison, S.p.A.*, 664 F.2d 356, 212 USPQ 327 (3d Cir. 1981) ("Proof of one of the disclosed utilities suffices to meet the statutory utility requirement."); *Chisholm-Ryder Col., Inc. v. Mecca Bros., Inc.*, 217 USPQ 1322 (W.D. N.Y. 1983) ("The utility requirement is satisfied if the invention is useful for some purpose described in the specification, even though it may not be useful for other purposes indicted therein.").

The fact that cytokines in general have a diverse spectrum of functions is legally irrelevant. Thus, the asserted utility of IL-B50 is specific and not generally applicable to all proteins. Further, the asserted utility of IL-B50 is substantial and provides a real world benefit to the public due to the involvement of B-cells and T-cells in immunotherapy and autoimmunity.

The Examiner cites to *In re Fisher*, 421 F.3d 1365 (2005) and asserts:

disclosing a substantial utility means "show[ing] that an invention is useful to the public as disclosed in its current form, not that it may be useful at some future date after further research. Simply put, to satisfy the 'substantial' utility requirement, an asserted use must show that the claimed invention has a significant and presently available benefit to the public.

Applicants respectfully submit that the facts of this case can be clearly distinguished from those of *In re Fisher*. In *Fisher*, the claims at issue were directed to ESTs (expressed sequence tags) of genes with no known functions. Further, all of the utilities asserted by *Fisher* were equally applicable to all ESTs (for example, the use of ESTs to identify polymorphisms, to design oligonucleotide probes or primers, and to measure mRNA expression levels). Unlike Applicants, *Fisher* did not claim any utility which was specific and could distinguish the claimed ESTs from other ESTs. Moreover, *Fisher* did not present any evidence to support the asserted uses as "presently beneficial and hence practical." *Id.* at 1377. In contrast, the use of IL-B50 to stimulate hematopoietic cells such as T-cells and B-cells was beneficial in 1998 as it provides a target for immunotherapy and autoimmunity.

In addition, the Examiner asserts at p. 4 of the Office Action that the previously filed Sali Declaration was vague and unclear, because the Examiner was not sure what Dr. Sali was referring to when he said "I was asked to review the '318 provisional application to determine if a person of skill in the art at the time that the application was filed would have considered the statement relating to the ability of IL-B50 to stimulate or inhibit T cells and B cells to be credible." It is clear from the declaration and the '318 provisional application that

Dr. Sali was referring to p. 9 of the '318 provisional application. A Supplemental Declaration is being filed concurrently to clarify any ambiguities addressed by the Examiner.

The Examiner asserts that "[i]n order to discover how to use the claimed antibodies, a skilled practitioner would have to perform significant amount of further research to discover what is, if any that particular effect that IL-B50 shares with IL-7. Thus, at the time of filing, to employ antibodies of the instant invention...would be to use such antibodies as the object of further research, which has been determined by the courts to be a utility which, alone, does not support patentability." Office Action at p. 5.

Applicants draw the Examiner's attention to the attached non-precedential opinion by the Board of Patent Appeals and Interferences ("the Board"): *Ex parte Hedrick*, Appeal No. 2005-1922, Application No. 09/770,528 (mailed September 22, 2005) (Exhibit B). In *Ex parte Hedrick*, the claims on appeal were directed to binding compounds, *e.g.* antibodies, which specifically bound to IL-1 δ . The claims were rejected by the Examiner for lack of utility. The Board reversed. The specification asserted that IL-1 δ "likely plays a role in modulating of local and systemic inflammatory processes" (*see Ex parte Hedrick*, p. 7). The Examiner found the asserted utility to be non-specific and insubstantial, apparently based on "the lack of disclosure regarding the specific role that IL-1 δ plays in inflammation," and the fact that the specification did not specify whether the IL-1 δ could contribute to or inhibit inflammation (*see Ex parte Hedrick*, pp. 9-10). The Board found the Examiner's concerns to be unwarranted, and stated:

Once it has been accepted that IL-1 δ either contributes to or inhibits the inflammatory response, it seems that those skilled in the art would recognize the claimed binding compounds as useful. Specifically, if IL-1 δ contributes to inflammation, those skilled in the art would recognize the claimed compounds to be useful in inhibiting inflammation. On the other hand, if IL-1 δ inhibits inflammation, those skilled in the art would recognize the claimed compounds to be useful in promoting inflammation.

Thus, it would seem that the examiner's acceptance of IL-1 δ as having a role in inflammation would require recognizing that IL-1 δ -binding compounds are useful for either inhibiting or promoting inflammation. The examiner has not argued that compounds that promote inflammation lack utility, or that compounds that inhibit inflammation lack utility. Since the examiner apparently accepts that the claims compounds will have one of these two activities, the disclosure that IL-1 δ has a role in inflammation seems adequate to support utility.

(see *Ex parte Hedrick*, p. 10). The Board also specifically found that the use of post-filing evidence demonstrating the accuracy of the asserted utility was acceptable, and noted that in the context of pharmaceutical inventions "useful" necessarily includes the expectation of further research and development:

We agree with the examiner that utility must be shown as of the effective filing date. See *In re Brana*, 51 F.3d at 1567 n.19, 34 USPQ2d at 1441 n. 19. However, post-filing evidence is acceptable where it is relied on, not to supplement the specification's disclosure, but to show the accuracy or inaccuracy of a statement in the specification. (see *Ex parte Hedrick*, pp. 10-11).

Applicants respectfully submit that the facts of this case are at least as compelling as the facts in *Ex parte Hedrick*. The '318 provisional application discloses that IL-B50 is a cytokine structurally related to IL-7. Furthermore, the '318 provisional application discloses that IL-B50 is expected to stimulate the proliferation of T-cells and B-cells, similar to IL-7. The '318 provisional application also states that IL-B50 may be useful in the treatment of immune disorders, e.g. T-cell immune deficiencies, chronic inflammation, or tissue rejection. '318 provisional application at p. 13, lines 1-4. Moreover, as discussed in the previous response, post-filing literature confirms the accuracy of the asserted utility; see pp. 9-10 of the previous response. Therefore, a finding of utility is warranted in this case.

As shown by the evidence discussed above and by the concurrently filed Supplemental Declaration of Dr. Andrej Sali, a specific, substantial, and credible utility for the claimed invention is disclosed in the '318 provisional application. Similarly, because the claimed invention was described as having a clear and well-established utility for the reasons set forth above, one of ordinary skill in the art clearly would have known how to use the claimed invention as of September 1998.

Because the claimed invention has priority to the '318 provisional application, the '520 patent is not available as prior art. Applicants respectfully request that this rejection be reconsidered and withdrawn.

Conclusion

Applicants respectfully submit that this application is in condition for allowance.

Respectfully submitted,



Gloria M. Fuentes

Attorney for Applicants
Registration No. 47,580

Schering-Plough Corporation
2000 Galloping Hill Road
Patent Department, K-6-1, 1990
Kenilworth, NJ 07033
Tel: (908) 298-2266
Fax: (908) 298-5388